California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENNEGGER, GOVERNOR

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be competed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If a hospital pharmacy dispenses prescriptions for outpatient use, a Community Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
(Please use an additional sheet if necessary)

1. _____ RPH # _____ Exp. Date: _____
2. _____ RPH # _____ Exp. Date: _____
3. _____ RPH # _____ Exp. Date: _____
4. _____ RPH # _____ Exp. Date: _____
5. _____ RPH # _____ Exp. Date: _____
6. _____ INT # _____ Exp. Date: _____
7. _____ INT # _____ Exp. Date: _____
8. _____ INT # _____ Exp. Date: _____
9. _____ TCH # _____ Exp. Date: _____
10. _____ TCH # _____ Exp. Date: _____
11. _____ TCH # _____ Exp. Date: _____
12. _____ TCH # _____ Exp. Date: _____
13. _____ TCH # _____ Exp. Date: _____
14. _____ TCH # _____ Exp. Date: _____
15. _____ TCH # _____ Exp. Date: _____

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes	No	N/A	
☐	☐	☐	The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)
☐	☐	☐	The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)
☐	☐	☐	The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
☐	☐	☐	The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)
☐	☐	☐	The pharmacy sink has hot and cold running water. (CCR 1714)
☐	☐	☐	The pharmacy has a readily accessible restroom. (CCR 1714)
☐	☐	☐	Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2)
☐	☐	☐	Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
☐	☐	☐	The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)
☐	☐	☐	Does the pharmacy compound sterile injectable drugs? (If yes, complete section 23 – "Compounding Sterile Injectable Drugs".)
☐	☐	☐	The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

☐☐☐ The pharmacy reports to the board within 30 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Delivery of Drugs

Yes No N/A

☐☐☐ Dangerous drugs and dangerous devices are only delivered to the licensed premise, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 11209(a))

☐☐☐ A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):

The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);

Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);

The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);

The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and

The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Drug Stock

Yes	No	N/A	
☐	☐	☐	The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22CCR 70263[q], CCR 1714[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Pharmacist-in-Charge (PIC)

Yes	No	N/A	
☐	☐	☐	The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)
☐	☐	☐	The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])
☐	☐	☐	The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)
☐	☐	☐	Is the PIC in charge of another pharmacy?
☐	☐	☐	If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐	☐	☐	Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113)
☐	☐	☐	Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1[d])

If yes, name the wholesaler or veterinary food-animal retailer. _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Duties of a Pharmacist

Yes No N/A

☐☐☐ The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are per formed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))

☐☐☐ The pharmacist as part of the care provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures, ordering drug therapy related laboratory tests, administering drugs or biologicals by injection, adjusting the drug regimen of a patient, and performing moderate or waived laboratory tests. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

☐☐☐ The pharmacist dispenses emergency contraceptive pursuant to statewide protocol found in 16 CCR 1746.

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, 4023.5, CCR 1726)

☐☐☐ All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

☐☐☐ The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

☐☐☐ Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

☐☐☐ A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

Yes No N/A

☐☐☐ The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

☐☐☐ The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

9. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ Pharmacists provide oral consultation (B&PC 4052[a][7], CCR 1707.2):

whenever the prescription drug has not been previously dispensed to the patient;

whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;

upon request; and

whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

Yes No N/A

☐☐☐ The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

☐☐☐ The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

☐☐☐ Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Prescription Requirements

Yes No N/A

☐☐☐ Prescriptions are complete with all the required information. (B&PC 4040, 4070)

☐☐☐ Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direction supervision of a pharmacist. (B&PC 4070, CCR 1717)

☐☐☐ If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (B&PC 4071)

☐☐☐ If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)

☐☐☐ The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])

☐☐☐ Facsimile prescriptions are received only from prescriber's office. (B&PC 4040[c])

☐☐☐ Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])

Yes No N/A

☐☐☐ With the exception of those prescriptions written under H & S 11159.2, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&S 11164[a])

☐☐☐ All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&S 11164[a] [1] , 11120[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ The prescription label contains all the required information. (B&PC 4076)

☐☐☐ Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076)

☐☐☐ The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])

☐☐☐ Generic substitution is communicated to the patient. (B&PC 4073)

☐☐☐ If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label. (B&PC 4115, CCR 1793.7, CCR 1712)

☐☐☐ The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

☐☐☐ The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership,

Yes No N/A

☐☐☐ The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)

☐☐☐ Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Refill Authorization

Yes No N/A

☐☐☐ Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

☐☐☐ Refills are documented. (CCR 1717)

☐☐☐ Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (B&PC 4064)

☐☐☐ Refills for Schedule II controlled substances are prohibited. (H&S 11200)

☐☐☐ Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply. (H&S 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR1711[c][2][A], 1711[c][3]

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

Yes No N/A

☐☐☐ Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ The record for quality assurance review for a medication error contains: (CCR 1711[e])

Date, location, and participants in the quality assurance review;

Pertinent data and other information related to the medication error(s) reviewed;

Findings and determinations; and

Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

☐☐☐ Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&S 11153)

☐☐☐ Even after conferring with the prescriber, the pharmacist does not dispens a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Prescription Transfer

Yes No N/A

☐☐☐ Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717[f][1-6])

☐☐☐ Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Substance Prescription Transfers

☐☐☐ For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

☐☐☐ For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[f], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

☐☐☐ All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐☐☐ The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

☐☐☐ If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

☐☐☐ If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

☐☐☐ Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Record Keeping Requirements

Yes No N/A

☐☐☐ A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):

Prescription records (CCR 4081[a])

Purchase Invoices for all prescription drugs (4081[b])

Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)

U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13)

Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)

Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

☐☐☐ Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4140, 4149)

Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;

Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.

The sale of 10 or fewer hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 11364, B&PC 4145)

☐☐☐ Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing (CCR 1707)

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. DEA Controlled Substances Inventory

Yes No N/A

☐☐☐ Inventory:

Is completed biennially (every two years). Date completed: _____ (21CFR 1304.11[b])

☐☐☐ Schedule II inventory is separate from Schedule 111, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])

☐☐☐ Is available for inspection for three years. (CCR 1718)

☐☐☐ Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (CFR 1304.04[h])

☐☐☐ Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])

☐☐☐ Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21CFR 1304.04)

☐☐☐ U.S. Official Order Form (DEA Form-222) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form-222. (21CFR 1305.03, 1305.12)

☐☐☐ When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form-222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

☐☐☐ When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form-222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22,1988] 503. B&PC 4160)

☐☐☐ When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

Yes No N/A

☐☐☐ The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

☐☐☐ All Schedule II through IV controlled substance dispensing data successfully transmitted to CURES weekly. (H&SC 11165[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ A faxed prescription for a Schedule II controlled substance is dispensed **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

☐☐☐ An oral prescription for a schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form. The licensed facility provides the pharmacy with a copy of the prescriber signed order when available. (21 CFR 1306.11[f], H&SC 11167.5)

☐☐☐ An electronically transmitted order for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed after the pharmacist produces, signs and dates the hard copy prescription on a form of the pharmacy's design. The licensed facility forwards to the dispensing pharmacist a copy of the order signed by the prescriber when available. (21 CFR 1306.11[f], H&SC 11167.5

☐☐☐ If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (21 CFR 1306.13[a])

Yes No N/A

☐☐☐ The pharmacist maintains records of each partial filling (filled within 60 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill". (21 CFR 1306.13[b], CCR 1745)

☐☐☐ The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&S 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

☐☐☐ All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR1717.4)

☐☐☐ Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (1717.4[e])

☐☐☐ All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (1717.4[c])

☐☐☐ Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (1717.4[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

20. Automated Dispensing/Delivery Devices

Yes No N/A

☐☐☐ Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

☐☐☐ The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342)

☐☐☐ For an "automated drug delivery system" located in a skilled or intermediate care facility licensed by the Department of Public Health, the following is required:

Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H&SC 1261.6[d][1])

A pharmacist reviews the order and patient's profile prior to the drug being removed. (H&SC 1261.6[e][2])

Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

Yes No N/A

☐☐☐ If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])

Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

21. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430)

☐☐☐ A log is maintained for drugs pre-packed for future dispensing. (CCR 1716.2)

☐☐☐ Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

22. Refill Pharmacy

Yes No N/A

☐☐☐ Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

☐☐☐ Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

Yes No N/A

☐☐☐ Some or all pharmacy refill orders are processed by another California licensed pharmacy. (1707.4[a])

If the answer is "yes" , name of refilling pharmacy(s) _____

If the answer to both questions above is “no” or “not applicable” go to section 22.

☐☐☐ Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (1707.4[a][1])

☐☐☐ Refill prescription label meets requirements of B&PC 4076 and shows the name and address of the refilling and or originating pharmacy. (1707.4[a][2])

☐☐☐ Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (1707.4[a][3])

☐☐☐ Both pharmacies maintain complete and accurate records or refill. (1707.4[a][4])

☐☐☐ Both pharmacies are responsible for accuracy of the refilled prescription. (1707.4[a][5])

☐☐☐ Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Policies and Procedures

Yes No N/A

☐☐☐ There are written policies and procedures in place for:

The pharmacist’s administration of immunizations by injection pursuant to a prescriber’s order; (B&PC 4052[a][5][A][iii])

Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license; (B&PC 4104[a])

Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy; (B&PC 4104[b])

Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])

Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist’s responsibilities for

checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR1717.1[e])

The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present. (B&PC 4059.5[f][1])

Compliance with Title 7 – Combat Methamphetamine Epidemic Act of 2005.

Reporting requirements to protect the public. (B&PC 4104)
Preventing the dispensing of a prescription drug that is contrary to the law. (B&PC 733)

Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition. (B&PB 733)

Yes No N/A

☐☐☐ Does your pharmacy employ the use of a common electronic file?

If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Compounding Sterile Injectable Drugs

a. Compounding Area for Parenteral Solutions

Yes No N/A

☐☐☐ Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1(a) and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

☐☐☐ The pharmacy has a designated area or cleanroom for the preparation of sterile products from a non-sterile source that has the following:

An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom; (B&PC 4127.7[a])

A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])

An ISO class 5 cleanroom (B&PC 4127.7[b]); and

A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])

Yes No N/A

☐☐☐ The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy's written policies and procedures. (CCR 1751.01[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Facility & Equipment Standards

Yes No N/A

☐☐☐ The compounding environment meets criteria specified in pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.01[a])

☐☐☐ Only those who are properly attired pursuant to (CCR 1751.4) are allowed in the cleanroom. (CCR 1751.01[b])

☐☐☐ All equipment used in the designated cleanroom is made of easily cleaned and disinfected material. (CCR 1751[c])

☐☐☐ Exterior workbench surfaces and other hard surfaces in the cleanroom, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (B&PC 1751.01[d])

☐☐☐ There are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

c. Policies and Procedures

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.02)

Compounding, filling, and labeling of sterile injectable compounds;

Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

Equipment and supplies;

Training of staff in preparation of sterile injectable products;
Training of patient and/or caregiver in the administration of compounded sterile injectable products;

Procedures for the handling and disposal of cytotoxic agents;

Quality assurance program; and

Record keeping requirements.

Yes No N/A

☐☐☐ Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.02 [b])

☐☐☐ If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following:

Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.02 [c][1]); and

All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.02 [c][2])

☐☐☐ Policies and procedures address the following: (CCR 1751.02 [c][3] [A-K])

Competency evaluation;

Storage and handling of products and supplies;

Storage and delivery of final products;

Process validation;

Personnel access and movement of materials into and near the controlled area;

Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (i.e., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations;

A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;
Sterilization; and

End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

d. Labeling

Yes No N/A

☐☐☐ The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2)

Telephone number of the pharmacy, unless dispensed for a hospital in-patient;

Name and concentrations of ingredients contained in the product;

Instructions for storage and handling; and

A special label that states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

e. Record Keeping Requirements

Yes No N/A

☐☐☐ Pharmacy records for sterile injectable products produced for future use (pursuant to section 1716.1), in addition to record requirements of section 1716.2, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.3[a])

☐☐☐ Records for sterile products compounded from one or more non-sterile ingredients are maintained for at least three years and contain the following: (CCR 1751.3[b])

The training and competency evaluation of employees in sterile product procedures;

Refrigerator and freezer temperatures;

Certification of the sterile compounding environment;

Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);

Inspection for expired or recalled pharmaceutical products or raw ingredients; and

Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

☐☐☐ The pharmacy maintains records of validation processes as required by Section 1751.7(b) for three years. (CCR 1751.3[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

f. Attire

Yes No N/A

☐☐☐ When preparing cytotoxic agents, gowns and gloves are worn.(CCR 1751.4[a])

Yes No N/A

☐☐☐ When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used:

Cleanroom garb is donned and removed outside the designated area; (CCR 1751.4[b][2])

Individuals in the cleanroom wear a low-shedding coverall, head cover, facemask, and shoe covers; (CCR 1751.4[b][1])

No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.4[b][3])

Head and facial hair is kept out of critical area or covered (CCR 1751.4[b][4]); and

Gloves of low-shedding material are worn. (CCR 1751.4[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

g. Training of Staff, Patient, and Caregiver

Yes No N/A

☐☐☐ Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.5[a])

☐☐☐ The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.5[b])

☐☐☐ Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.5[c])

☐☐☐ The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.5[d])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.5[e])

☐☐☐ The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.5[e][1][A-J])

Aseptic technique;

Pharmaceutical calculations and terminology;

Sterile product compounding documentation;

Quality assurance procedures;

Proper gowning and gloving technique;

General conduct in the controlled area;

Cleaning, sanitizing, and maintaining equipment used in the controlled area;

Sterilization techniques; and

Container, equipment, and closure system selection.

Yes No N/A

☐☐☐ Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.5[e][2])

☐☐☐ Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. (CCR 1751[e][2])

☐☐☐ Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751[e][2])

☐☐☐ Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

h. Disposal of Waste Material

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures for the disposal of infectious material and/or materials containing cytotoxic residues. (CCR 1751.6)

☐☐☐ The procedures include the cleanup of spills and are in conformance with local health jurisdiction. (CCR 1751.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

i. Quality Assurance and Process Validation

Yes No N/A

☐☐☐ There is a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

☐☐☐ The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-5])
Cleaning and sanitization of the parenteral medication preparation area;

Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and

are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens;

The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

Steps to be taken in the event of a drug recall; and

Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1716.2[a][3]).

Yes No N/A

☐☐☐ Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

☐☐☐ The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

☐☐☐ The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

☐☐☐ The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

☐☐☐ Completed medium samples are incubated. (CCR 1751.7[b])

☐☐☐ If microbiological growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

☐☐☐ Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whatever aseptic techniques are observed. (CCR 1751.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

j. Reference Materials

Yes No N/A

☐☐☐ Current reference materials are maintained or available to the pharmacy on the drugs and chemicals used in parenteral therapy services and all parenteral therapy manufacturing, dispensing, distribution, and counseling services provided. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

25._Compounding Non-Sterile Drug Products

a. Compounding Unapproved Drugs for Prescriber Office Use (CCR 1716.1):

Yes No N/A

☐☐☐ Pharmacy compounds unapproved drugs for prescriber office use based upon a reasonable quantity

☐☐☐ Establishing reasonable quantity is based on the intended use of the compounded medication and nature of the prescriber's practice.

☐☐☐ Compounded medications means medications actively compounded by the pharmacy supplying them to a prescriber.

☐☐☐ Prescriber office use means application or administration in the prescriber's office or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Record Keeping Requirements – Compounding for Future Furnishing (CCR1716.2)

Yes No N/A

☐☐☐ For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

The date of preparation (compounding);

The name of the manufacturer, the lot number of all components used to compound the product;

The expiration date of each component (if not available, the source and date of purchase)

A pharmacy lot number or identification number;

☐☐☐ A master formula for each compounded drug product in a readily retrievable form to also include:

The amount of each component, compounding directions, etc;

A beyond-use-date not to exceed 180 days or the shortest expiration date of any component (unless the pharmacy possesses stability data for each product compounded by the pharmacy beyond the 180 days);

The signature/initials of the person(s) who compounded the drug product; and

The signature/initials of the pharmacist who checked the final product.

☐☐☐ The final quantity of drug product compounded (number of individual units by weight or volume and package size);

Yes No N/A

☐☐☐ Status/disposition of any quarantined compounded drug products to also include release date; and

☐☐☐ Status/disposition of any compounded drug products that failed to meet standards for quality purity or strength.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

26. NUCLEAR PHARMACY

Yes No N/A

☐☐☐ All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ The pharmacy possesses a current Sterile Compounding Permit (B&P 4127) and is compliant with CCR 1751. (must also complete section 21)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834
(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements, CA 92673
(800) 498-0911 Ext. 5
www.lawtechpublishing.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street
Manchester, NH 03103
Phone: (888) 492-7341
Fax: 877-508-6704

CURES
4949 Broadway
Sacramento, CA 95820
Phone: (916) 319-9062
Fax: (916) 319-9448
http://www.ag.ca.gov/bne

CURES Patient Activity Report Request Forms:
http://www.ag.ca.gov/bne/trips.php

PRESCRIBER BOARDS:

Medical Board of California
2005 Evergreen St., Suite 1200
Sacramento, CA 95815
(800) 633-2322
(916) 263-2382
fax: (916) 263-2944
http://www.mbc.ca.gov

Dental Board of California
2005 Evergreen St., Suite 1550
Sacramento, CA 95815
(916) 263-2300
fax: (916) 263-2140
http://www.dbc.ca.gov

Board of Registered Nursing
1625 N. Market Blvd., Suite N217
Sacramento, CA 95834
(916) 322-3350
fax: (916) 574-7697
http://www.rn.ca.gov/

Board of Optometry
2420 Del Paso Road, Suite 255
Sacramento, CA 95834
(916) 575-7170
fax: (916) 575-7292
http://www.optometry.ca.gov/

Osteopathic Medical Board of California
1300 National Drive, Suite 150
Sacramento, CA 95834
(916) 928-8390
fax: (916) 928-8392
http://www.ombc.ca.gov

Physician Assistant Committee
2500 Evergreen St., Suite 1100
Sacramento, CA 95815
(916) 561-8780
fax: (916) 263-2671
http://www.pac.ca.gov

Board of Podiatric Medicine
2005 Evergreen St., Suite 1300
Sacramento, CA 95815
(916) 263-2647
fax: (916) 263-2651
http://www.bpm.ca.gov

Veterinary Medical Board
2005 Evergreen St., Suite 2250
Sacramento, CA 95815
(916) 263-2610
fax: (916) 263-2621
http://www.vmb.ca.gov

FEDERAL AGENCIES:

Food and Drug Administration
– Industry Compliance
http://www.fda.gov/oc/industry/centerlinks.html#drugs

The Drug Enforcement Administration may be contacted at:

DEA Website: http://www.deadiversion.usdoj.gov
Online Registration – New Applicants:
http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm
Online Registration - Renewal:
www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm
Registration Changes (Forms):
http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html
DEA Registration Support (all of CA):
(800) 882-9539
Online DEA 106 Theft/Loss Reporting:
https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp
Online DEA 222 Controlled Substance Ordering System (CSOS): http://www.deaecom.gov/

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-5406

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
(888) 415-9822 or (213) 621-6960 (Registration)
(213) 621-6942
(Diversion or Investigation)

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251
Diversion or Investigation: (510) 637-5600

DEA – Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (530) 246-5043

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
Registration: (888) 415-9822 or
(213) 621-6960
Diversion or Investigation: (951) 328-6200

DEA - Sacramento
4328 Watt Avenue
Sacramento, CA 95821
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (916) 480-7250

DEA – San Diego and Imperial Counties
4560 Viewridge Avenue
San Diego, CA 92123-1637
Registration: (800) 284-1152
Diversion or Investigation: (858) 616-4100

DEA – San Francisco
450 Golden Gate Avenue, 14th Floor
San Francisco, CA 94102
Registration: (888) 304-3251
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